UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,675	03/07/2001	Rebecca E. Cahoon	BB-1240	3886

7590 12/06/2002

William R Majarian
E I du Pont de Nemours & Company
Legal Patents
Wilmington, DE 19898

EXAMINER
NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
1652	17

DATE MAILED: 12/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/786,675	Cahoon et al.
Examiner	**Art Unit**
Nashaat T. Nashed	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 15, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *15, 21, 22, and 32-48* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15, 21, 22, and 32-48* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application has been amended as requested in the communication filed October 15, 2002. Accordingly, claims 1-14, 16-20, and 23-31 have been canceled, new claims 32-48 have been entered, and claims 15, 21 and 22 have been amended.

Claims 15, 21, 22, and 32-48 are pending and under consideration.

Applicant's election without traverse of Group VI, claims 15, 21, 22, and 32-48, in Paper No. 15 is acknowledged. New Claims 32-48 are drawn to elected Group VI.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15, 21, 22, and 32-48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose the nucleic acid sequence of SEQ ID NO: 11 from a library prepared from corn nucellus tissue five days after silking encoding the amino acid sequence of SEQ ID NO: 12, see table 2 on page 16. Based on a reasonable sequence homology, the polypeptide of SEQ ID NO: 12 is sought to be a farnesyltransferase (FT) β-subunit which is a generic asserted utility at best. FT is a class of enzymes which catalyze the transfer of a farnesyl moiety to a specific acceptor molecule. FT's are heterodimeric proteins in plants and animal and their subunits are known to have no enzymatic activity by themselves. Although the specification teaches an α-subunit of FT from corn, see Table 2 on page 16, the specification indicates that the α- and β-subunits are isolated from different libraries constructed from different tissues at a different stage of growth of a corn plant. The specification fails to show the two disclosed subunits interact together or function as a catalyst of any reaction. Plants and animals have many FTs that are expressed at different stages of their growth in different tissues, and each FT is expected to have a specific substrate(s) and biological function. The specification does not disclose a specific function of the polypeptides of SEQ ID NO: 12, its relationship to any plant disease or characteristics, or any specific real world use. It is noted that the application indicates that a defects in FT activity enhances plant hormone abscisic acid which in turn leads to decrease of water loss *via* transpiration, see page 1, last paragraph, but this is known for a specific FT associated with a specific biological function. The specification, however, fails to show that disabling the expression of the nucleic acid

sequence of SEQ ID NO: 11 would lead to a decrease in water loss *via* transpiration in a corn plant. The specification does not teach the biological role or function of the FT comprising the specific β-subunit of SEQ ID NO: 12. The specification appears to describe generic functions for the protein, and nucleic acid. The utility of the nucleic acid is said to be used in a method to decrease the FT activity in corn which may leads to a plant resistant to drought, but the specification does not establish any relationship between SEQ ID NO: 12 and such a characteristics. One of ordinary skill in the art would not expect that decreasing any FT activity in corn would lead a drought resistant plant. It appears that the main utility of the polypeptide and nucleic acid as of the priority date for the application is to carry out further research to identify the biological function and possible use. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 21, 22, and 32-48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 15, 21, 22 and 32-48 are rejected under 35 U.S.C. § 112, first paragraph. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the enzymatic activity of the polypeptide of SEQ ID NO: 12 and it use, let alone all possible variant of nucleic sequences encoding or amino acid sequences having 80%, 85%, and 95% of SEQ ID NO: 12. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the

prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any nucleic acid encoding or polypeptide sequence having 80%, 85%, and 95% sequence homology to the amino acid sequence of SEQ ID NO: 12 from any biological and man-made source. That include all possible insertion, deletion substitution and combination thereof mutants. The specification provides guidance and examples in the form of an assay to isolate the nucleic acid of SEQ ID NO: 11 from a cDNA library from corn, identify the open reading frame which encodes the amino acid sequence of SEQ ID NO: 12, and compare the amino acid sequence of SEQ ID NO: 12 to other sequences in the protein data bank to identify a generic function for the polypeptide, i. e., β-subunit of a farnesyltransferase (see examples). While molecular biological techniques and genetic manipulation to make the claimed constructs are known in the prior art and the skill of the artisan are well developed, knowledge regarding the FT α-subunit which forms a functional heterodimer with the β-subunit of SEQ ID NO: 12, the reaction which said heterodimer catalyzes, the biological sources of the nucleic acid sequences encoding FT and having 80%, 85%, and 95% sequence homology to the β-subunit SEQ ID NO: 12 and its partner in catalysis, i. e., α-subunit, and the amino acid fragments or residues which can be deleted, inserted and substituted in SEQ ID NO: 12 without adverse effect on the chemical and/or biological activity of the β-subunit of SEQ ID NO: 12 is lacking. Thus, searching for an FT α- and β-subunits and/or a nucleic acid encoding FT α- and β-subunits of which the β-subunit has 80%, 85%, and 95% sequence homology to SEQ ID NO: 12 is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a nucleic acid encoding the heterodimeric FT wherein the β-subunits has 80%, 85%, and 95% sequence homology to SEQ ID NO: 12 is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic, cDNA or man-made nucleic acid libraries, identifying the coding regions of the FT α- and β-subunits and the substrate(s) which the heterodimer utilizes, where the expectation of obtaining the desired FT is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the biological source of the heterodimeric α- and β-subunits, the substrate which the heterodimer utilizes, three dimensional structure of the heterodimer and/or the amino acid residues which can be inserted, deleted or substituted without affecting the biological and/or chemical activity of the FT heterodimer. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 15, 21, 22, and 32-34, 37-46 and 48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) The phrases "having farnesyltransferase activity" in claim 32 and 44 render the claim indefinite and confusing because the polypeptide of SEQ ID NO: 12 is disclosed in the specification as the β-subunit of the heterodimer αβ-FT. The subunit does not have any catalytic activity on its own.

(b) The phrase "a complement of the nucleotide sequence" in claim 32(b) lacks sufficient antecedent basis in the claim. For examination purposes only, the claim is interpreted as if it contains "of (a)" after the word "sequence".

(c) The phrase "transforming a cell with polynucleotide" in claim 39 renders the claims indefinite and confusing. A cell can be transformed with a vector or a polynucleotide comprising several control sequences such as origin of replication, promoter and termination sequences. The polynucleotide of claim 32 does not contain any control sequences.

(d) Claim 15 is a confusing method because the preamble of the claim does not match the result of the method and the claim may be interpreted as a various independent methods. The method is drawn to selecting a nucleic acid sequence that affect the level of farnesyltransferase in plant cell by introducing a nucleic acid to a plant cell (step B), measuring the level of FT activity (step c), and comparing the level of activity to a cell that does not contain said nucleic acid. The word "introducing" in the contest of the claim is confusing because it could mean transforming a cell with the nucleic acid which may lead to enhanced expression or disabling a natural gene in a plant cell (two different and distinct methods). A third interpretation to the word "introducing" is decreasing the expression of FT activity by antisense inhibitor. The three method are distinct from one another and should be separated because they require different and distinct chemical compound to carry out the method. The last step of the method claim, i. e., step (d) is a comparison step and not identifying step as required by the preamble of the method.

(e) The phrase "substantial portion" in claim 21 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

(f) The method of claim 22 is inoperable because a 30 contagious nucleotide bound to any nucleic acid is expected to melt at a temperature ~40 °C. It should be noted that any nucleic acid can hybridize under some conditions to any other nucleic acid. In order to have selectivity for the nucleic acid encoding FT activity applicant must identify specific hybridization conditions.

(g) The phrase "a method of altering the level of expression" in claim 48 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The construct of claim 38 comprising the complete sequence encoding only a β-subunit of FT. One of ordinary skill in the art would not expect transforming a host cell with said nucleic acid would increase the expression of the β-subunit of FT of SEQ ID NO: 12 and not the heterodimer.

(h) Claims 33, 34,37-43, 45, and 46 are included in these rejection because they are dependent on rejected claim and do not cure its deficiencies.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner